Exhibit 6

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS INC., MYLAN SPECIALTY L.P., AND MYLAN INC., Plaintiffs, v. SANOFI-AVENTIS U.S. LLC, SANOFI S.A., AVENTIS PHARMA S.A., AND SANOFI-AVENTIS PUERTO RICO INC. Defendants.	Civil Action No. 23-836-MRH

FEDERAL TRADE COMMISSION'S BRIEF AS *AMICUS CURIAE*

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Regulations

Defendant Sanofi[1] has moved to dismiss a complaint filed by Plaintiff Mylan[2] for failure to state a claim. Mylan's complaint alleges that Sanofi monopolized the market for injectable insulin glargine in part by abusing an FDA regulatory process known as Orange Book listing. Sanofi seeks to dismiss these allegations on the basis that delays in Mylan's FDA approval process cannot be attributed to Sanofi's Orange Book listings. The FTC takes no position on Mylan's specific factual allegations. As a general matter, however, improper Orange Book listings like those alleged here can cause significant harm to competition, and that harm can extend beyond the delay caused directly by the improper listing.

The FTC has a long history of working to ensure that Orange Book listing abuses do not harm competition for pharmaceuticals. Under the Hatch-Waxman Act, a company marketing a branded drug under a New Drug Application (NDA) must list certain of its patents in the FDA's "Orange Book" database. Specifically, the company must list any patents that (1) could be infringed by a follow-on drug, and (2) claim either the drug itself or an approved method of using the drug. The possibility of infringement alone is not sufficient for listing in the Orange Book if a patent does not also meet one of the latter two criteria. For example, patents claiming manufacturing processes or packaging may be infringed by a competing drug product but do not satisfy the other statutory criteria for listing. This strict statutory limitation serves an important purpose because listing a patent in the Orange Book has significant consequences for competition. If a brand company timely sues a generic competitor for infringement of an Orange Book listed patent (after receiving required notice from the generic applicant), it triggers an

[1] The defendants include multiple Sanofi corporate entities. The FTC takes no position on jurisdiction or liability with regard to any specific corporate entity, and uses the term "Sanofi" to describe the defendants collectively.

[2] Plaintiffs also include multiple Mylan corporate entities, and the FTC refers to them collectively as "Mylan."

automatic statutory bar on the FDA's ability to approve the competitor's drug for up to 30 months.

When triggered by an appropriately listed patent, this 30-month stay reflects Congress's intent to balance the interests of brand and generic drug manufacturers by facilitating the resolution of certain types of patent disputes before generic or other competing follow-on products are introduced. But when this stay is triggered by a patent that does not meet the statutory listing criteria, the stay merely delays consumer access to a competing product that might reduce prices, improve quality and access, or both. Given the high cost of many drugs, even a short delay in competition can have enormous consequences for consumers' access to cost-effective medications. The prospect of an automatic 30-month block on competition (and accompanying higher profits) can incentivize brand companies to wrongfully list ineligible patents in the Orange Book. These companies take advantage of the FDA's long-standing position that it has a purely ministerial role in the listing process. The FDA verifies that the brand's representations meet the statutory listing criteria but does not independently assess whether those representations are accurate.

Mylan alleges that Sanofi inappropriately listed numerous patents that did not meet the Orange Book statutory listing requirements. In a separate case, the First Circuit has held that private plaintiffs plausibly alleged that at least one of those patents, No. 8,556,864, was improperly listed. *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 8-9 (1st Cir. 2020). The FTC takes no position on whether the specific patents at issue in this case were properly listed.[3] To the extent that any such patents were improperly listed, however, such listings can

[3] At the motion-to-dismiss stage, a complaint's allegations are assumed to be true. *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009) ("When there are well-pleaded factual allegations, a court (Continued…)

cause substantial harm to competition and to consumers. And this harm can extend beyond the delay from the 30-month stay: improper listings can distort the competitive process by affecting the planning and incentives of potential competitors. Indeed, the prospect of a 30-month stay may deter rivals from developing lower-cost generic products, permanently depriving the market of competition and access to affordable medications. Improperly listing an ineligible patent, either on its own or alongside other anticompetitive conduct, may therefore constitute illegal monopolization.

INTEREST OF THE FTC

The FTC is an independent agency charged by Congress with enforcing competition and consumer protection laws.[4] It exercises primary responsibility for federal antitrust enforcement in the pharmaceutical industry.[5] The Commission has substantial experience evaluating pharmaceutical competition under the Hatch-Waxman Act and has brought numerous enforcement actions challenging anticompetitive abuses of the Hatch-Waxman framework.[6]

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should assume their veracity . . ."). Accordingly, the FTC's recitation of facts in this *amicus* brief are taken directly from Mylan's complaint and do not represent a view on what Mylan may ultimately prove.

[4] 15 U.S.C. §§ 41–58.

[5] For a summary of the FTC's actions in the pharmaceutical industry, see Fed. Trade Comm'n, Overview of FTC Actions in Pharmaceutical Products and Distribution (Oct. 2023), https://www.ftc.gov/system/files/ftc_gov/pdf/Overview-Pharma.pdf.

[6] *See, e.g. FTC v. Actavis, Inc.*, 570 U.S. 136 (2013); *Impax Lab'ys., Inc. v. FTC*, 994 F.3d 484 (5th Cir. 2021); *FTC v. AbbVie Inc.*, 976 F.3d 327 (3d Cir. 2020); *FTC v. Shkreli*, 581 F. Supp. 3d 579 (S.D.N.Y. 2022); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402 (E.D. Pa. 2015).

The FTC has long been concerned about Orange Book listing abuses. The Commission first examined the effect of Orange Book listings on competition as part of a 2002 study.[7] Around the same time, the FTC entered an order against Biovail Corporation for, among other things, wrongfully listing a patent in the Orange Book to block generic competition. Decision and Order, *In re Biovail Corp.*, FTC Dkt. No. C-4060 (Oct. 2, 2002). The FTC has also filed amicus briefs on improper Orange Book listings in private litigations relating to the drugs Buspirone and Xyrem. *See* Mem. of Law for Fed. Trade Comm'n as *Amici Curiae*, *In re: Buspirone Patent Litig.*, No. 1:01-md-1410-JGK (S.D.N.Y. Jan. 8, 2002) (No. 31) and Mem. of Law for Fed. Trade Comm'n as *Amicus Curiae*, *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, No. 1:21-cv-691 (GBW) (D. Del. Nov. 15, 2022) (No. 227). The FTC has also issued a policy statement explaining that improper listing in the Orange Book may, in some situations, constitute an unfair method of competition.[8] On November 7, 2023, the FTC sent letters to 10 drug manufacturers notifying them of more than 100 improperly listed Orange Book patents.[9]

Although this case involves a dispute between private parties, the FTC submits this amicus brief because the allegations in the Complaint may have broader implications for the Commission's competition mission and for consumers.

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[7] *See* Fed. Trade Comm'n, Generic Drug Entry Prior to Patent Expiration: An FTC Study, 39-52 (2002) ("FTC Study"), https://www.ftc.gov/reports/generic-drug-entry-prior-patent-expiration-ftc-study.

[8] *See* Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book (Sept. 14, 2023) ("FTC Orange Book Statement"), https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf.

[9] *See* Press Release, FTC Challenges More Than 100 Patents As Improperly Listed in the FDA's Orange Book (Nov. 7, 2023), *available at* https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book?ref=biztoc.com.

BACKGROUND

The Hatch-Waxman framework and Orange Book patent listings

Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act,[10] to "'speed the introduction of low-cost generic drugs to market' and promote competition." *FTC v. AbbVie, Inc.*, 976 F.3d 327, 339 (3d Cir. 2020) (quoting *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013)). The first company to seek approval for a novel drug must file a New Drug Application and go through the FDA's "full-length" application process, which requires extensive safety and efficacy data. *See AbbVie*, 976 F.3d at 338–39. The Act then allows subsequent companies to seek FDA approval for similar drugs through a streamlined process. This in turn allows them to get to market faster and offer their competing products at a lower cost. The net result is significant health care savings for consumers.

The Hatch-Waxman Act's streamlined application process offers two pathways. A company seeking to market an essentially identical generic version of a brand drug can file an Abbreviated New Drug Application (ANDA) under Section 505(j). *See id.* at 339. An ANDA applicant does not need to do its own safety or efficacy studies. Instead, the applicant can rely on the FDA's finding of safety and effectiveness for the brand drug so long as it demonstrates to the FDA that, among other requirements, the product has the same active ingredient, labeling, conditions of use (except those protected by patents or exclusivity), strength, dosage form, and route of administration and is bioequivalent to the brand drug (in very general terms, meaning that it is absorbed into the body in the same way). *See* 21 U.S.C. § 355(j)(2)(A).

[10] Pub. L. No. 98-417, 98 Stat. 1585 (1984), 21 U.S.C. § 355, 35 U.S.C. § 271.

Alternately, a company seeking to market a modified version of an existing brand drug—such as one with a "new indication or new dosage form"—can file an NDA under Section 505(b)(2) of the FD&C Act. *AbbVie*, 976 F.3d at 339. A 505(b)(2) applicant must "produce some data, including whatever information is needed to support the modifications." *Id.* (cleaned up). Because a 505(b)(2) applicant does not need to re-do all of the brand company's testing, it saves substantial costs, likely resulting in lower prices for consumers.

The Hatch-Waxman framework also has provisions "that encourage the quick resolution of patent disputes" for certain types of patents. *AbbVie*, 976 F.3d at 339. During the initial NDA, "the Hatch-Waxman Amendments and FDA regulations direct brand manufacturers to file information about their patents." *Caraco Pharm. Lab'ys., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). Specifically, a brand manufacturer must list in the Orange Book all patents that meet two criteria. "First, the patent must be one for which infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug." *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 641 F. Supp. 3d 85, 89 (D. Del. 2022), *aff'd*, 60 F.4th 1373 (Fed. Cir. 2023) (cleaned up). Second, the patent must claim either "the drug for which the [brand] submitted the [application] or . . . a method of using such a drug." *Caraco*, 566 U.S. at 405 (discussing 21 U.S.C. § 355(b)(1)). "[A] patent claim that fails to explicitly include the drug actually makes neither type of claim on the drug." *United Food & Com. Workers Loc. 1776 v. Takeda Pharm. Co. Ltd.*, 11 F.4th 118, 134–35 (2d Cir. 2021). Further, it is improper to list patents in the Orange Book that claim parts of a product other than the drug. For example, "patents claiming packaging . . . are not covered by [the listing regulations], and information on these patents must not be submitted to FDA." 21 C.F.R. § 314.53(b)(1).

The patents that meet the Orange Book criteria of claiming the drug or method of using the drug are thus a narrower set than those that could be asserted in a patent infringement suit. Indeed, in another case involving one of the patents at issue in this litigation, the First Circuit held that a patent claiming part of a drug's delivery system was not properly listed in the Orange Book because it did not explicitly claim the drug. *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 8 (1st Cir. 2020).

Once a brand applicant has received NDA approval, the FDA publishes the patent numbers, expiration dates, and use codes submitted by the company "in a fat, brightly hued volume called the Orange Book." *Caraco*, 566 U.S. at 405–06. The FDA's role in this listing process is "purely ministerial." *Organon Inc. v. Mylan Pharms., Inc.*, 293 F. Supp. 2d 453, 458–59 (D.N.J. 2003).[11] Any subsequent ANDA or 505(b)(2) applicant must then review the listed patents and make one of several certifications "that its proposed [] drug will not infringe" them. *Caraco*, 566 U.S. at 406; *see also AbbVie*, 976 F.3d at 339. If the applicant seeks to market its product before the expiration date of a listed patent, it must make a "paragraph IV certification" that the patent is either invalid or the applicant's product will not infringe it. 21 U.S.C. §§ 355(b)(2)(A)(iv), 355(j)(2)(A)(vii)(IV); *AbbVie*, 976 F.3d at 339.

A paragraph IV certification constitutes an act of statutory infringement of the relevant patent. *Caraco*, 566 U.S. at 407; *AbbVie*, 976 F.3d at 339. If the brand company timely files a patent suit within 45 days of receiving notice of the paragraph IV certification, among other

[11] After Sanofi listed its patents in the Orange Book, the FDA implemented a new regulatory process for approving therapeutically equivalent versions of biologic products, known as biosimilars, under the Biologics Price Competition and Innovation Act of 2009 ("BPCI Act"), Pub. L. No. 111-148, 124 Stat. 804 (2010). Mylan's product was ultimately deemed a biologic under this framework. *See* Compl. ¶¶ 136-38. For purposes of evaluating Mylan's monopolization claim, however, the Orange Book listing process was the applicable regulatory framework when Sanofi listed the patents at issue. *See* Compl. ¶¶ 128-29.

statutory criteria, it receives an automatic 30-month stay during which the FDA cannot approve the competitor's application (unless the competitor prevails in litigation before then). 21 U.S.C. §§ 355(c)(3)(C), 355(j)(5)(B)(iii). This 30-month stay is not a "stay" in the traditional sense. It is not ordered or enforced by a court, but instead is an automatic hold on the FDA's ability to proceed with final approval of a generic application if paragraph IV patent litigation is initiated within the specified timeframe.

Sanofi, its Lantus products, and the patents listed in the Orange Book

According to the allegations in Mylan's complaint, Sanofi markets Lantus, which is the brand name for an insulin glargine injection used to treat diabetes. Compl. ¶¶ 88-89, 92. A predecessor company to Sanofi first received approval from the FDA in 2000 to market Lantus. Compl. ¶¶ 82, 86. Along with this application, the predecessor company submitted one patent, Patent No. 5,656,722 (the '722 patent) for listing in the Orange Book. Compl. ¶¶ 87, 90. In 2007, the FDA approved a supplement to the NDA for a disposable, pre-filled autoinjector pen device called the Lantus SoloSTAR. Compl. ¶ 96. The '722 patent, as extended by a 6-month period of pediatric exclusivity, expired in February 2015. Compl. ¶¶ 84, 85, 93. At that point, without any other patents listed in the Orange Book, there would have been no basis for a 30-month stay of the FDA's approval of a follow-on version of Lantus.

In 2013, however, prior to expiration of the '722 patent, Sanofi began to list other patents in the Orange Book for Lantus. Compl. ¶¶ 118-120. Mylan alleges that two of the patents listed in 2013 claimed only the vial version of the Lantus product and were not applicable to SoloSTAR. Compl. ¶¶ 98-113, 120. Mylan further alleges that Sanofi subsequently listed additional patents that related to injector pens but did not claim insulin glargine or the SoloSTAR product. Compl. ¶¶ 114-121. Mylan contends that all of these patents were improperly listed in

the Orange Book. In a separate antitrust case brought by a class of direct purchasers of insulin glargine, the First Circuit reinstated a complaint alleging that Sanofi had improperly listed one of the 2013 patents in the Orange Book. *Lantus*, 950 F.3d at 8. The Lantus SoloSTAR pen remains highly profitable today. In 2021, Lantus SoloSTAR sales totaled approximately $2.8 billion in sales to Medicare Part D patients alone.[12]

Mylan and Semglee

According to Mylan's complaint, in 2013, Mylan partnered with Biocon Limited ("Biocon"), an Indian company that had previously launched a biosimilar version of insulin glargine called Basolog in India. Compl. ¶ 124. Biocon had already started the process of obtaining regulatory approval for an insulin glargine product from the FDA when the companies formed their joint venture. *Id.* At that time, the only patent listed in the Orange Book was the '722 patent, which could only block generics until February 2015 when a period of pediatric exclusivity that attached to the patent was set to expire. *Id.* ¶ 126. In the same month that the joint venture was announced, Sanofi began to list the 2013 patents described above in the Orange Book. *Id.* ¶ 125.

Mylan claims that its application process was complicated by the likelihood that the FDA would at some point deem insulin glargine a biologic product and require an entirely different type of application pursuant to the Biologics Price Competition and Innovation Act ("BPCIA"). *Id.* ¶¶ 128-133. From 2013 to 2016, Mylan states that it sought regulatory guidance from the FDA concerning whether a traditional ANDA approach, 505(b)(2) application, or alternative pathway would be required. *Id.* ¶ 128. Mylan alleges that the prospect of a 30-month stay created

[12] *See* Centers for Medicare & Medicaid Services, Medicare Part D Spending by Drug, *available at* https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug/data.

significant risk that the FDA would change the regulatory status of insulin glargine before it could grant Mylan approval, thereby causing Mylan to switch to a different application process.

In April 2017, Mylan submitted a 505(b)(2) application for its injectable insulin glargine product, called Semglee. Sanofi promptly sued Mylan for infringement of its 2013 Orange Book patents, triggering the 30-month stay on FDA approval of its application. Compl. ¶ 129. The FDA ultimately approved Mylan's 505(b)(2) application in June 2020. Upon approval, by operation of the Public Health Services Act, Mylan's application was deemed an approved biologics license application. Compl. ¶ 136. Mylan then had to apply for Semglee to be considered an interchangeable biosimilar with Lantus. Compl. ¶¶ 136-139. In May 2023, Mylan brought this suit alleging that, as part of a course of anticompetitive conduct, Sanofi improperly listed a large number of patents in the Orange Book, which resulted in delays in FDA approval for Semglee.

ARGUMENT

Improper Orange Book listings raise serious competition concerns because they may illegally delay generic entry. Under the Hatch-Waxman framework, a brand pharmaceutical company can obtain a 30-month stay to block a competitor simply by listing a patent in the Orange Book and suing for infringement within a specified timeframe. Given the enormous profit margins of many brand drugs, even small delays in competition can be extremely lucrative to the brand company—but deny consumers access to affordable medications. The FTC takes no position on whether the Sanofi patents at issue were improperly listed. But, as a general matter, improper listings can cause significant harm to competition and consumers. As such, improperly

listing a patent in the Orange Book can constitute illegal monopolization or part of an illegal course of monopolistic conduct under Section 2 of the Sherman Act.[13]

The Hatch-Waxman scheme reflects a careful balance between encouraging innovation in drug development and accelerating the availability of lower-cost competing drugs.[14] The Orange Book listing process is part of this balance. As the Third Circuit has observed, "[t]he automatic, 30-month stay creates tension with the Hatch Waxman Act's procompetitive goals." *AbbVie*, 976 F.3d at 340. For this reason, Congress strictly limited the types of patents that can trigger the Hatch-Waxman litigation process and its automatic 30-month stay of FDA approval. This special treatment is afforded only to patents claiming "the drug for which the [brand] submitted the [NDA]" or "a method of using such drug." *See, e.g.*, 21 U.S.C. §§ 355(b)(1), (c)(2); *Caraco*, 566 U.S. at 405. And Congress confirmed this limitation in 2003 when it created a mechanism to remove any listed patent that does not claim either (a) the brand drug, or (b) "an approved method of using the drug." 21 U.S.C. § 355(j)(5)(C)(ii)(I).

Brand manufacturers, however, can evade the statutory limitation and improperly obtain a stay by "exploit[ing] the FDA's determination that it cannot police patent claims." *Caraco*, 566 U.S. at 424. Indeed, the FDA takes a "purely ministerial" role in the listing process. *Organon*, 293 F. Supp. 2d at 458–59.[15] Each brand company is responsible for making determinations

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[13] Though not relevant in a private case like this one, improper Orange Book listings can also constitute an unfair method of competition under Section 5 of the FTC Act. *See* FTC Orange Book Statement at 5.

[14] *See* H.R. Rep. No. 98-857, at 14–15 (1984).

[15] *See also American Biosci., Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001) (FDA "administers the Hatch-Waxman Amendments in a ministerial fashion simply following the intent of the parties that list patents"); *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 371 (S.D.N.Y. 2002) ("[T]he FDA's actions are non-discretionary and do not reflect any decision as to the validity of the representations in an Orange Book listing.").

about its patent listings.[16] The FDA accepts the brand's patent descriptions and "does not independently assess the patent's scope or otherwise look behind the description authored by the brand." *Caraco*, 566 U.S. at 406–07. It similarly "does not attempt to verify the accuracy of the use codes that the brand manufacturers supply." *Id.* at 405. Nor does the FDA have the ability to remove improperly listed patents.[17] There is thus no independent referee to prevent a company from inappropriately listing patents that do not meet the Orange Book criteria. As a result, the antitrust laws play an indispensable role in protecting consumers from unwarranted Orange Book claims and automatic stays.

An improper listing can substantially harm competition and consumers: By listing a patent in the Orange Book and then filing an infringement suit, a brand can block competition for up to two-and-a-half years regardless of the scope or validity of the patent and regardless of whether it meets the statutory listing criteria. *AbbVie*, 976 F.3d at 371 (noting the "the collateral injury the Hatch-Waxman Act's 30-month stay invariably inflicts"); *Caraco*, 566 U.S. at 419 ("An overbroad use code therefore throws a wrench into the FDA's ability to approve generic drugs as the statute contemplates."). Additionally, an improper listing may work a more subtle harm by deterring potential competitors or distorting their decision-making. Faced with a 30-month lag on receiving a return on investment, a generic company may elect to pursue an alternative generic drug product.[18] This means that unwarranted Orange Book claims may

[16] *See* FTC Orange Book Statement at 1.

[17] The FDA's regulations allow any person to "dispute the accuracy of patent information listed in the Orange Book," but FDA will then only "request that the brand verify the information." *Caraco*, 566 U.S. at 407 n.1.

[18] *See* FTC Orange Book Statement at 3-4.

deprive consumers of lower-priced competing drugs even long after any 30-month stay would expire.

As early as the late 1990s, "evidence mounted that some brands were exploiting this statutory scheme to prevent or delay the marketing of generic drugs." *Caraco*, 566 U.S. at 408.[19] Consumers suffer from this practice both because they are forced to continue paying non-competitive prices and because they are deprived of the ability to choose between products. *United States v. Brown Univ.*, 5 F.3d 658, 675 (3d Cir. 1993) ("Enhancement of consumer choice . . . has [] been acknowledged as a procompetitive benefit"), *citing Nat'l Collegiate Athletic Ass'n v. Board of Regents of Univ. of Oklahoma*, 468 U.S. 85, 102 (1984).[20]

The language of the Hatch-Waxman Act specifies that only patents claiming "a drug" or "a method of using" a drug can be listed. 21 U.S.C. § 355(b)(1)(A)(viii). Mylan alleges that Sanofi's 2013 patents do not meet that standard. Compl. ¶¶ 114-17. Reviewing a motion to dismiss in a separate case, the First Circuit found the allegations sufficient to claim one of these patents was improperly listed because it did "not mention the drug for which the [application] was submitted . . . and it was improper for Sanofi to have submitted it for listing in the Orange Book as a drug claiming [] insulin glargine." *Lantus*, 950 F.3d at 8.

If Sanofi improperly listed its injector pen patents in the Orange Book, it might have caused significant harm to competition. Sanofi allegedly listed its new patents the same month that Mylan announced its partnership with Biocon, which had previously introduced an insulin glargine product in India and had filed an investigational new drug application. Compl. ¶¶ 123-

[19] *See also* FTC Study at 39-52 (ideifying numerous instances in which the 30-month stay was abused to block competition).

[20] *See* FTC Study at 9 (outlining the lower prices and substantial savings that typically result from generic or follow-on competition).

127. Mylan allegedly had not anticipated a potential 30-month stay of FDA approval because Sanofi's previously listed patents had expired or covered formulations that differed from Mylan's. Compl. ¶ 126. And Mylan further alleges that its planning was complicated by the prospect that the FDA would eventually deem insulin glargine a biologic product, thus changing its application process. Compl. ¶¶ 128-133. According to Mylan, the unexpected listing of Sanofi's additional patents "short-circuited" its plans, disturbing "the foundation of the timing decisions affecting Mylan's application[.]" Compl. ¶ 132. The complaint alleges that this led to significant delay in the approval of Mylan's product.

To the extent that Sanofi contends that Mylan could have avoided harm from an improper Orange Book listing by making different, more expedient business decisions, that is no defense. The antitrust laws did not require Mylan to foresee or preempt an anticompetitive scheme. *FTC v. Shkreli*, 581 F. Supp. 3d 579, 636-37 (S.D.N.Y. 2022) (describing how a pharmaceutical executive's actions were responsible for delays in approval despite arguments that generic competitors could have taken alternative actions to expedite the regulatory process). Generic drug companies "need not undertake herculean efforts to overcome significant anticompetitive barriers specifically erected to prevent their entry into a market." *Id.* at 637.

If Sanofi's actions harmed the competitive process, they may constitute illegal monopolization. Monopolization requires proof of "the willful acquisition or maintenance of [monopoly] power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966). This requires proof that the defendant has engaged in anticompetitive conduct to "foreclose competition, to gain a competitive advantage, or to destroy a competitor." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 482–83 (1992) (citing *United States v.*

Griffith, 334 U.S. 100, 107 (1948)). As described above, improper Orange Book listings can harm competition and consumers by enabling brand companies to block competition for up to two-and-a-half years—regardless of whether the patent is valid or infringed by the competitor's product. Thus, courts have consistently recognized that improperly listing patents in the Orange Book may constitute an "improper means" of maintaining or acquiring monopoly power. *See, e.g.*, *Lantus*, 950 F.3d at 7 (quoting *Town of Concord v. Bos. Edison Co.*, 915 F.2d 17, 21 (1st Cir. 1990)); *see also United Food & Com. Workers Local 1776 v. Takeda Pharm*. Co., 11 F.4th 118, 134–136 (2d Cir. 2021).[21]

Further, as a legal matter, Sanofi's Orange Book listings can be viewed as one part of an overarching monopolistic scheme. *See* Compl. ¶ 3 ("Sanofi's multifaceted monopolization scheme includes three distinct parts, each of which is comprised of multiple types of separately illegal practices."). Rather than approaching multiple antitrust claims as "completely separate and unrelated lawsuits . . . plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each." *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962); *see also LePage's Inc. v. 3M*, 324 F. 3d 141, 162 (3d Cir. 2003) ("[C]ourts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation."). Improper Orange Book listings can therefore be evaluated in combination with other regulatory abuses, such as sham litigation, as part of an overall strategy to delay the approval or entrance of generic competition. Compl. ¶ 3.[22]

[21] FTC Orange Book Statement at 5-6.

[22] The FTC takes no position on whether the other alleged regulatory abuses are in fact anticompetitive here.

CONCLUSION

For the foregoing reasons, to the extent Sanofi improperly listed patents in the Orange Book, this may have caused substantial harm to competition and may constitute violation of the antitrust laws.

Dated: November 20, 2023

Respectfully submitted,

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